

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

VACCINES FOR CHILDREN PROGRAM

HEPATITIS B

VACCINES TO PREVENT HEPATITIS B

The purpose of this resolution is to revise the previous resolution to incorporate the use of a combined hepatitis A and hepatitis B vaccine for use in persons 18 years of age.

VFC resolution 2/00-3 is repealed and replaced by the following:

Eligible Groups

**All previously unvaccinated children and adolescents
from birth through 18 years.***

*Twinrix is only indicated for persons 18 years and older, and only children 18 years of age are eligible for Twinrix® thru the VFC program.

Eligible Groups for Post-Exposure Immunoprophylaxis

- 1. Infants of HBsAg-positive mothers:**
Infants born to mothers who are HBsAg-positive should receive appropriate doses of hepatitis B vaccine and hepatitis B immune globulin (HBIG) (0.5 mL) within 12 hours of birth and should complete the 3-dose hepatitis B vaccine series according to the recommended schedule.
- 2. Persons whose sexual partners have acute hepatitis B:**
All previously unvaccinated sexual partners of persons with acute hepatitis B virus infection should receive the hepatitis B vaccine series and a single dose of HBIG (0.06 mL/kg) if HBIG can be started within 14 days of the last sexual contact. The recommended schedule for hepatitis B vaccination of these persons is: 0, 1, 6 months; 0, 1, 4 months; or 0, 2, 4 months.
- 3. Persons with percutaneous or mucosal exposure to blood that contains (or might contain) HBsAg:**
For unvaccinated persons who have percutaneous or mucosal exposure to blood, the hepatitis B vaccine series should be initiated. If the source of exposure is HBsAg-positive, HBIG (0.06 mL/kg) should also be administered within 7 days of exposure.
- 4. Unvaccinated infants whose primary caregiver has acute hepatitis B.** Infants whose primary caregiver has acute hepatitis B should receive a single dose of HBIG (0.5 mL) and complete the 3-dose hepatitis B vaccine series according to the recommended schedule.

Recommended Hepatitis B Vaccine Schedule

**The routine recommended schedule for hepatitis B vaccination
for infants born to HBsAg-negative mothers is:**

Dose	Vaccination Schedule Options†	
	Age of child	Age of child
HepB-1	Birth (0 months)	1-2 months
HepB-2	1-2 months	4 months
HepB-3	6-18 months	6-18 months

NOTE: Premature infants of HBsAg negative mothers should receive the first dose of hepatitis B vaccine series when the infant weighs ≥ 2 kg or is 2 months of age, including infants who remain hospitalized.

NOTE: The combination hepatitis B and Haemophilus influenzae type B (Hib) vaccine (COMVAX)* is licensed for use at 2, 4, and 12-15 months of age. Because of concerns about potential suppression of the immune response to the Hib component with subsequent doses, COMVAX cannot be used for hepatitis B vaccine doses at birth or one month of age, and can only be used after 6 weeks of age. This vaccine may be used whenever administration of any components of the combination are indicated and if other components are not contraindicated; or the separate Hepatitis B and Hib vaccines may be used. If single antigen hepatitis B vaccine is given at birth, 3 doses of hepatitis B containing combination vaccines can be given to complete the series starting after 6 weeks of age.

* Use of brand name is not meant to preclude the use of other licensed combined Hib/Hepatitis B vaccines.

†3 dose hepatitis B vaccine schedule with pediatric/adolescent formulation

Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection†:

Infant born to mother known to be HBsAg* positive	
	<i>Age of infant</i>
HepB-1	Within 12 hours of birth
HBIG ‡	Within 12 hours of birth
HepB-2	1-2 months
HepB-3	6 months

* HBsAg = Hepatitis B surface antigen.

‡Hepatitis B immune globulin (HBIG) — 0.5 ml administered intramuscularly at a site different from that used for vaccine.

Preterm infants

For preterm infants who weigh < 2 kg at birth, the initial vaccine dose should not be counted as part of the 3-dose series, and three doses of vaccine should be administered beginning when the infant is \geq 2 kg or 2 months of age.

NOTE: The combination hepatitis B and Haemophilus influenzae type B (Hib) vaccine (COMVAX)❖ is licensed for use at 2, 4, and 12-15 months of age. Because of concerns about potential suppression of the immune response to the Hib component with subsequent doses, COMVAX cannot be used for hepatitis B vaccine doses at birth or one month of age, and can only be used after 6 weeks of age. This vaccine may be used whenever administration of any components of the combination are indicated and if other components are not contraindicated; or the separate Hepatitis B and Hib vaccines may be used. If single antigen hepatitis B vaccine is given at birth, 3 doses of hepatitis B containing combination vaccines can be given to complete the series starting after 6 weeks of age.

❖ Use of brand name is not meant to preclude the use of other licensed combined Hib/Hepatitis B vaccines.

† 3 dose hepatitis B vaccine schedule with pediatric/adolescent formulation

Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection†:

Infant born to mother with an unknown HBsAg* status

	<i>Age of infant</i>
HepB-1	Within 12 hours of birth
HBIG ‡	If mother found to be HBsAg positive, infant should receive HBIG within 7 days of age
HepB-2	1-2 months
HepB-3	6 months

* HBsAg = Hepatitis B surface antigen.

† Mother should be tested for HBsAg.

‡Hepatitis B immune globulin (HBIG) -- 0.5 ml administered intramuscularly at a site different from that used for vaccine.

Preterm infants: if a preterm infant who weighs < 2 kg at birth, is found to be born to an HBsAg positive mother and receives HBIG before 7 days of age, the initial vaccine dose should not be counted as part of the 3-dose series, and three doses of vaccine should be administered beginning when the infant is \geq 2 kg or 2 months of age.

NOTE: The combination hepatitis B and Haemophilus influenzae type B (Hib) vaccine (COMVAX)▲ is licensed for use at 2, 4, and 12-15 months of age. Because of concerns about potential suppression of the immune response to the Hib component with subsequent doses, COMVAX cannot be used for hepatitis B vaccine doses at birth or one month of age, and can only be used after 6 weeks of age. This vaccine may be used whenever administration of any components of the combination are indicated and if other components are not contraindicated; or the separate Hepatitis B and Hib vaccines may be used. If single antigen hepatitis B vaccine is given at birth, 3 doses of hepatitis B containing combination vaccines can be given to complete the series starting after 6 weeks of age.

▲ Use of brand name is not meant to preclude the use of other licensed combined Hib/Hepatitis B vaccines.

† 3 dose hepatitis B vaccine schedule with pediatric/adolescent formulation

Catch-Up Vaccination

The ACIP recommends catch-up vaccination of previously unvaccinated children and adolescents less than 19 years of age. The recommended dosing schedules for unvaccinated children and adolescents are:

Option 1: 3 dose pediatric/adolescent formulation for all children < 19 years of age

Dose	Usual Interval
Hep B-1	----
Hep B-2	1 month
Hep B-3	4-6 months

Option 2: 2 dose adult formulation (Recombivax HB®, Merck & Co.)* for children 11-15 years of age

Dose	Usual Interval
HepB-1	----
HepB-2	4-6 months

Option 3: 3 dose adult formulation (Twinrix®, GlaxoSmith Kline) * for persons 18 years of age

Dose	Usual Interval
HepB-1	----
HepB-2	1 month
HepB-3	5 months

* Use of brand name is not meant to preclude use of other brands when recommended for 2 dose administration to adolescents 11-15 years of age or 3 dose administration to persons 18 years of age.

Dosage Intervals

Vaccine	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3 (when applicable)	Minimum interval from dose 1 to 3 (when applicable)
Hepatitis B (3 dose schedule with pediatric/adolescent formulation)	4 weeks	8 weeks	16 weeks†
Hepatitis B (2 dose schedule with adult formulation for children 11-15 years of age)	16 weeks	n/a	n/a
Hepatitis B (3 dose schedule as combined Hepatitis A/Hepatitis B vaccine)	1 month	5 months	6 months
†The third vaccine dose should not be given to infants before 24 weeks of age.			

Recommended Dosages

Refer to product package inserts.

Contraindications and Precautions

The following conditions are contraindications to the administration of hepatitis B vaccine:

1. **Anaphylactic reaction to a previous dose of hepatitis B vaccine.**
Further vaccination with hepatitis B and/or hepatitis B/Hib vaccine is contraindicated in persons with a history of anaphylaxis (severe allergic reaction) after a previous dose of hepatitis B and/or hepatitis B/Hib vaccine.
2. **Administration of COMVAX® vaccine or other hepatitis B/Hib vaccines to infants younger than 6 weeks of age.**
Combined hepatitis B/Hib vaccine must not be administered to infants younger than 6 weeks of age because of potential suppression of the immune response to the Hib component of the vaccine.
3. **Administration of Twinrix® vaccine to persons younger than 18 years of age.**
Combined hepatitis A/hepatitis B vaccine is not licensed for use in persons younger than 18 years of age
4. **Moderate or severe illnesses with or without fever.**

The following conditions are contraindications to the administration of hepatitis B immune globulin (HBIG):

1. **Anaphylactic reaction to a previous dose of any immune globulin preparation.**
2. **Serum immunoglobulin A deficiency.**

Adopted and Effective: 10-17-01

Note: Vaccines approved by the ACIP for inclusion in the VFC program are not available for use in the program until ACIP recommendations have been published and after the CDC has established a contract for the purchase of the vaccines.